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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/510,002 | 12/27/2005 | Kristen Briggs | G-175US03PCT | 7745 |
| 23557 | 7590 | 02/04/2008 | EXAMINER | |
| SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950 | | | LUKTON, DAVID | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1654 | | |
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| | | 02/04/2008 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/510,002 | BRIGGS ET AL. |
| | Examiner | Art Unit |
| | David Lukton | 1654 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 November 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 15-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 15-34 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

As pointed out by applicants (response 11/12/07), the examiner erred (Office action mailed 10/12/07) by neglecting to consider all pending claims. As pointed out by applicants, claims 15-34 are pending.

As such, this Office action supercedes the Office action mailed 10/12/07. Nevertheless, in order to avoid any confusion between Office actions, the numbering of groups begins with "5" in this Office action.

A restriction is imposed, as set forth below. First, however, the following subgenera are defined:

G9: The polypeptide comprises SEQ ID NO: 2, or the polypeptide comprises a fragment of SEQ ID NO: 2; or a salt or isoform or fused protein or functional derivative or circularly permuted derivative thereof;

G10: The polypeptide comprises SEQ ID NO: 4, or the polypeptide comprises a fragment of SEQ ID NO: 4; or a salt or isoform or fused protein or functional derivative or circularly permuted derivative thereof;

G11: The polypeptide comprises SEQ ID NO: 6, or the polypeptide comprises a fragment of SEQ ID NO: 6; or a salt or isoform or fused protein or functional derivative or circularly permuted derivative thereof;

G12: The polypeptide comprises SEQ ID NO: 8, or the polypeptide comprises a fragment of SEQ ID NO: 8; or a salt or isoform or fused protein or functional derivative or circularly permuted derivative thereof;

Restriction to one of the following inventions is required under 35 U.S.C. §121:

- 5) Claims 15-25, drawn to a method of treating a disease by administering a polypeptide, or an “active fraction” of a polypeptide.
- 6) Claims 26-29, drawn to a method of treating a disease by administering a polynucleotide.
- 7) Claim 30, drawn to a polypeptide or an “active fraction” of a polypeptide.
- 8) Claims 31-34, drawn to a polynucleotide or a vector or a cell or a method of using a polynucleotide.

The claimed inventions are distinct from one another.

Inventions 7 and 5 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the peptides could be used for in vitro assays, or for treating diseases that are not “metabolic related”. Nevertheless, in the event that Group 7 is elected, and claims therein found allowable, the corresponding method of use claims will be rejoined therewith for further examination.

Claims 31 and 26 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product

as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)).

In the event that Group 6 or 8 is elected, the application will likely be transferred to another examiner; that examiner will then decide whether rejoining or further restriction among claims 26-29 & 31-34 is called for.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect species/subgenera (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that Group 5 is chosen for initial examination, election each of the following is required:

a) a specific disease; and

b) one of the following: (i) G9 or (ii) G10 or (iii) G11 or (iv) G12 or (v) an “active fraction” of a polypeptide.

In the event that Group 7 is chosen for initial examination, election of one of the following

is required: (i) G9 or (ii) G10 or (iii) G11 or (iv) G12 or (v) an "active fraction" of a polypeptide.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.
PRIMARY EXAMINER